K101730

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Warsaw, IN 46581-0708
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ZIMMER

Summary of Safety and Effectiveness

DEC - 3 2010

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Bradley W. Strasser Associate, Regulatory Affairs Telephone: (574) 372-4780 Fax: (574) 372-4605
Date:	14 September 2010
Trade Name:	*Longevity*® IT Highly Crosslinked Polyethylene Constrained Liner
Common Name:	Total Hip Prosthesis
Classification Name and Reference:	Hip joint metal/polymer constrained cemented or uncemented prosthesis. 21 CFR § 888.3310
Product Code:	KWZ – Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer
Predicate Device:	*Trilogy*® *Longevity* Constrained Liner, manufactured by Zimmer, Inc., K071718, cleared 13 July 2007 *Continuum*™ and *Trilogy* Integrated Taper (IT) Acetabular Systems, manufactured by Zimmer, Inc., K091508, cleared 11 September 2009
Device Description:	The *Longevity* Integrated Taper (IT) Constrained Liner is a modular acetabular shell liner intended to capture the femoral head of a total hip prosthesis to reduce the incidence of joint dislocation. The liners feature integral polyethylene "fingers" reinforced with a modular *Tivanium*® ring to capture the mating femoral head. The *Longevity* IT Constrained Liners are intended to mate with

	Continuum and *Trilogy* IT acetabular shells.
Intended Use:	The *Longevity* IT Constrained Liner is indicated as a component of a total hip prosthesis in primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered.
Comparison to Predicate Device:	The *Longevity* IT Constrained Liners are manufactured from the same materials and processes as their predicates. The subject device also has the same intended use and constraining mechanism as the predicate *Trilogy Longevity* Constrained Liner. The *Longevity* IT Constrained Liners have the same liner locking mechanism as the predicate *Continuum* and *Trilogy* IT Acetabular System Polyethylene Liners.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-Clinical testing was conducted on the proposed device per FDA's Guidance Document, "*Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis*". This testing demonstrated that the *Longevity* IT Constrained Liners performed as intended and met all acceptance criteria.

The *Longevity* IT Constrained Liner design and geometry were evaluated to demonstrate that the proposed device met performance requirements and is as safe and effective as its predicate. This information and testing data formed the basis for a determination of substantial equivalence.

Specific Non-clinical Testing Completed:

- Head Pull-Out Fatigue Test
- Rim Impingement Fatigue Test
- Static Head Pull-Out Test
- Static Rim Impingement Lever-Out Test
- Liner Locking Mechanism Strength Analysis
- Anatomic Fatigue Analysis
- Constrained Liner Wear Performance
- Liner Durability and Backside Wear
- Temperature Effects on Liner Assembly
- Interaction of MRI with World Cup Implants

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 3 2010

Zimmer, Inc.
% Mr. Bradley W. Strasser
Associate, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K101730
Trade/Device Name: *Longevity*® IT Highly Crosslinked Polyethylene Constrained Liners
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: November 5, 2010
Received: November 8, 2010

Dear Mr. Strasser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC - 3 2010

510(k) Number (if known): K101730

Device Name:

Longevity® IT Highly Crosslinked Polyethylene Constrained Liner

Indications for Use:

The *Longevity* IT Constrained Liner is indicated as a component of a total hip prosthesis in primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101730